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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,199	05/18/2001	Masaki Hirashima	0020-4867P	5173

2292 7590 06/29/2004

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,199	HIRASHIMA ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-11 and 16* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/18/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Alignment*.

DETAILED ACTION

Re: Hirashima *et al*
Priority Date: 19 November 1998

1. The amendment filed 4/2/2004 is acknowledged and entered into the record. Accordingly, claims 12-15 are canceled without prejudice or disclaimer.

2. Claims 1-11, and 16 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

4. The Information Disclosure Statement filed 5/18/2001 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claims 6-9 and 16 under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant's arguments with regard to "partial sequences" and "prevention" are moot in view of the amendment of the claims to remove such limitations. However, applicant's arguments concerning insufficient in vivo data is not deemed persuasive and the rejection is maintained for the reasons of record. Applicant argues that the references relied upon by the examiner to show unpredictability of correlating in vitro data with in vivo success are limited to exception cases (see page 8 of response). Applicant further states that "once efficacy of a certain chemical compound is proven *in vitro*, the corresponding efficacy *in vivo* can be demonstrated with high probability." Applicant's arguments have been carefully

considered but are not deemed persuasive to overcome the rejection of record. First these arguments are not deemed persuasive because these are arguments of counsel, which are not supported by any facts or evidence. Applicant's have not shown that the culturing conditions of their system are any different from those found in the majority of in vitro conditions as taught by both Dermer and Freshney, and therefore to say that the references are "exceptional cases" is unsupported. One of skill in the art can reasonably assume that the culturing conditions taught in the instant specification are no different from those commonly found in other laboratories and therefore the conditions described by both Freshney and Dermer would also be found in the instant case. Secondly, the references relied upon are general teachings which show that the use of in vitro data although an important step in moving from bench to bedside, does not always equate to efficacy as argued by the applicant, because the environment and the conditions of tissue culture do not adequately replicate the in vivo environment. Therefore testing in vivo must be performed in order to confirm the findings in vitro. Thus the correlation between in vitro and in vivo data cannot be as simply correlated as argued by the applicant.

Applicant further argues that other US Patents have issued that only provide in vitro experimentation but have claims drawn to pharmaceutical compositions for the treatment of HIV infection, and therefore concludes based on these patents that in vitro data sufficiently correlates to in vivo data. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. It is not the job of the examiner to question the validity of other issued US patents. Because the

prosecution history of those cases have not been examined, those cases may include declarations or affidavits that support the correlation of in vitro to in vivo data in those specific cases. No such declaration or affidavit has been provided in the instant case and therefore the unpredictability in correlating in vitro data to in vivo data has not been overcome. Moreover, the instant case is examined on its own merits and therefore the use of other patents to support the enablement of this application is not persuasive. Therefore the rejection under 35 USC 112, 1st paragraph is maintained.

New Arguments

Claim Rejections - 35 USC § 102

6. Claims 1-4,6-10, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill *et al* (Proc. Natl. Acad. Sci. 1993;90(2):537-541, cited in the IDS filed 5/18/2001). Hill *et al* teach an isolated polypeptide that comprises the amino acid sequence consisting of 103 amino acids at the C-terminal end of selenoprotein P. Hill *et al* also teaches a purified peptide that comprises the motif of both SEQ ID No: 1 and 2 (see figure 2 and attached sequence alignment). The limitations comprising claims 3 and 4, and 6-10, and 16 are also anticipated because these limitations are viewed as either inherent properties of the isolated protein or as intended uses of the protein and therefore do not breath any patentable weight into the claims. Furthermore, claim 1 of the instant invention is interpreted as being open, because of the "comprising" language and therefore the claims are anticipated.

7. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Sandstrom *et al* (Proc. Natl. Acad. Sci. 1993; 90(10):4708-12, cited in the IDS filed 8/20/2001).

Sandstrom *et al* teach a method of screening for cell-death inhibitory activity in a compound by incubating a candidate substance in a megakaryoblast culture system, which is cultured in a serum free medium supplemented with 0.1% albumin. The specification of the instant invention states that CEM and MOLt-4 cells are envisaged as types of megakaryoblast cell lines (see page 10).

Conclusion

8. No claim is allowed.

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

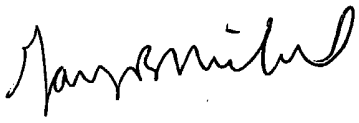
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
June 22, 2004

GARY NICKOL
PRIMARY EXAMINER



ALIGNMENTS

RESULT 1
A47327
selenoprotein P precursor [validated] - human
C;Species: Homo sapiens (man)
C;Date: 21-Sep-1993 #sequence_revision 01-Dec-1995 #text_change 15-Sep-2000
C;Accession: A47327; S42752
R;Hill, K.E.; Lloyd, R.S.; Burk, R.F.
Proc. Natl. Acad. Sci. U.S.A. 90, 537-541, 1993
A;Title: Conserved nucleotide sequences in the open reading frame and 3' untranslated re
A;Reference number: A47327; MUID:93133823
A;Accession: A47327
A;Molecule type: mRNA
A;Residues: 1-381 <HIL>
A;Cross-references: GB:Z11793; NID:g36425; PIDN:CAA77836.1; PID:g2654365
A;Experimental source: heart and liver
A;Note: in Genbank entry HSSELPM, release 117.0, PIDN:CAA77836.1, the selenocysteine UGA
R;Akesson, B.; Bellew, T.; Burk, R.F.
Biochim. Biophys. Acta 1204, 243-249, 1994
A;Title: Purification of selenoprotein P from human plasma.
A;Reference number: S42752; MUID:94191007
A;Accession: S42752
A;Molecule type: protein
A;Residues: 20-27,'X',29-33 <AKE>
A;Note: mature forms of 55K and 61K were detected in plasma; the protein was shown to co
C;Genetics:
A;Gene: GDB:SEPP1; SLNP
A;Cross-references: GDB:138278; OMIM:601484
A;Map position: 5q31-5q31
C;Function:
A;Description: may act as a free-radical scavenger
C;Superfamily: selenoprotein P
C;Keywords: extracellular protein; glycoprotein; heparin binding; liver; plasma; selenoc
F;1-19/Domain: signal sequence #status predicted <SIG>
F;20-381/Product: selenoprotein P #status experimental <MAT>
F;46,83,119,128,338/Binding site: carbohydrate (Asn) (covalent) #status predicted
F;59,300,318,330,345,352,367,369,376,378/Modified site: selenocysteine #status predicted

Query Match 95.6%; Score 130; DB 1; Length 381;
Best Local Similarity 92.9%; Pred. No. 8.8e-12;
Matches 26; Conservative 0; Mismatches 2; Indels 0; Gaps 0;

```
Qy       1 TGSAITXQCKENLPSLCSXQGLRAEENI 28
           |||||| |||||||||||| ||||||||||
Db     312 TGSAITCQCKENLPSLCSCQGLRAEENI 339
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fra